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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,075	09/22/2004	Racoul Donath	001227/0152	1247
69/095 7590 02/02/2009 STROOCK & STROOCK & LAVAN, LLP 180 MAIDEN LANE NEW YORK, NY 10038				
EXAMINER WOODALL, NICHOLAS W				
ART UNIT 3775		PAPER NUMBER		
MAIL DATE 02/02/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,075

Applicant(s)

DONATH, RAOUL

Examiner

Nicholas Woodall

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 9, 10 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9, 10 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the applicant's pre-appeal conference request received on 11/25/2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4, 5, 9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) and in view of Katz (U.S. Patent 5,989,254).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end, and a first channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged

orthogonal to the second channel. The set screw is threadingly engaged with the rear end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection element and the inner surface of the sealing cap and the device further comprising a securing element. Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connection element to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter further comprising a securing element in view of Katz in order to restrain the connection element to the pedicle screw. As discussed above Schaffler-Wachter discloses a device comprising complementary arresting means in order to secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the

sealing cap to the connection element. Because both Schaffler-Wachter and Gardner teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

4. Claims 1, 2, 4, 5, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) and in view of Nichols (U.S. Patent 6,090,111).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end,

and a first channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged orthogonal to the second channel. The set screw is threadingly engaged with the rear end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection element and the inner surface of the sealing cap and the device further comprising a securing element. Nichols teaches a device comprising a securing means that includes a snap-ring and groove configuration in order to retain the pedicle screw (column 4 lines 5-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter further comprising a securing element in view of Nichols in order to retain the pedicle screw. As discussed above Schaffler-

Wachter discloses a device comprising complementary arresting means in order to secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the sealing cap to the connection element. Because both Schaffler-Wachter and Gardner teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap of Schaffler-Wachter having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

5. Claims 15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end, and a first channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged orthogonal to the second channel. The set screw is threadingly engaged with the rear end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection. As discussed above Schaffler-Wachter discloses a device comprising complementary arresting means in

order to secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the sealing cap to the connection element. Because both Schaffler-Wachter and Gardner teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element. The device of Schaffler-Wachter as modified by Gardner disclose a device wherein the complementary arresting means are capable of allowing the sealing cap to being positioned at a first position, wherein a first set of bulges are engage with a first set of recesses, and moveable to a second position, wherein the first set of bulges and a second set of bulges are engaged with the first set of recesses and a second set of recesses, wherein the sealing cap is axially displaced along the connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap of Schaffler-Wachter having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person

ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) further in view of Katz (U.S. Patent 5,989,254).

The device of Schaffler-Wachter as modified by Gardner discloses the invention as claimed except for the device further comprising a securing element. Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connection element to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter as modified by Gardner further comprising a securing element in view of Katz in order to restrain the connection element to the pedicle screw.

Response to Arguments

7. Applicant's arguments, see the Pre-Brief Conference Request, filed 10/29/2008, with respect to the rejection(s) of claim(s) 1, 2, 4, 5, 9, and 18 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly found Gardner reference as discussed above. The examiner has provided new grounds of rejection making this office action non-final.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775
/Eduardo C. Robert/

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Supervisory Patent Examiner, Art Unit 3733